

**REMARKS**

The Examiner is thanked for the due consideration given the application

Claims 12-17 are pending in the application. The claims have been amended to better set forth the claimed invention and find support in, e.g., the drawing figures.

No new matter is believed to be added to the application by this amendment.

**Rejections Based on MORITA**

Claims 12-14 have been rejected under 35 USC §102(b) as being anticipated by MORITA. Claim 14 has been rejected under 35 USC §103(a) as being unpatentable over MORITA in view of CROSSMAN. Claims 15 and 17 have been rejected under 35 USC §103(a) as being unpatentable over MORITA in view of HIGGINS. Claim 16 has been rejected under 35 USC §103(a) as being unpatentable over MORITA in view of HIGGINS, and further in view of CROSSMAN.

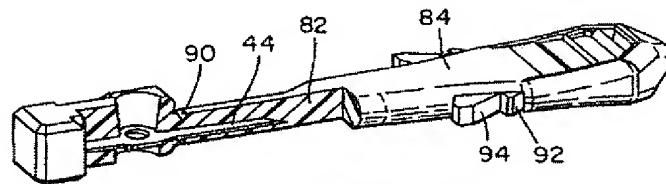
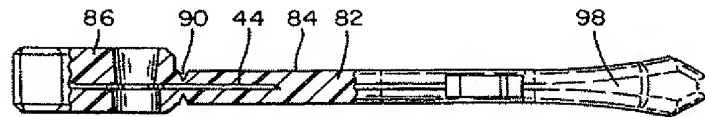
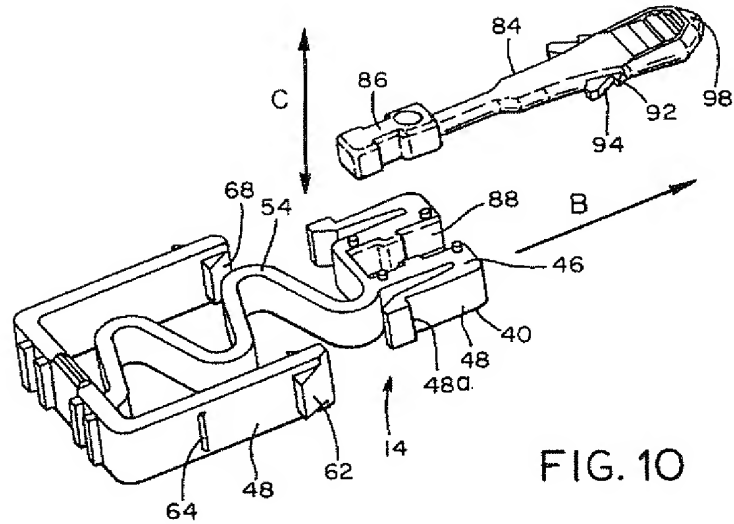
These rejections are respectfully traversed.

The present invention pertains to the design of a twist off cap or tab on a lancet that is illustrated, by way of example, in Figure 1 of the application, which is reproduced below.



In the present invention, a removable guard portion has an outer peripheral thickened rib describing a generally U- or C-shape. A central region is of thinner section than the rib and partly surrounded by the rib, and a tip encasing region encases the tip of the needle. The tip encasing region is of thicker section than the central region and is spaced from adjacent ends of the peripheral thickened region such that there are respective gaps therebetween bridged only by the thinner central section. This structure is reflected in independent claims 12 and 15 of the present invention.

MORITA pertains to a lancet assembly having a holder and a lancet structure which is incorporated with the holder. The Official Action refers to Figures 10-12 of MORITA, which are reproduced below.



These drawing figures of MORITA show show a lancet assembly in which the lancet is encased in an elongate stem which, at its end remote from the needle, has a raised peripheral rib to assist gripping.

The Official Action asserts that the peripheral rib is the "outer peripheral thickened region of U- or C-shape". The Official Action asserts that the body of the

stem is thinner than the peripheral rib and so constitutes the "central region of thinner section" and that the rear end of the stem of the cap constitutes the "further thickened region".

However, the Official Action misinterprets the claims by asserting that the "central region of thinner section" and the "further thickened region" actually have the same thickness. The Official Action justifies this by arguing that, while the stem of the cap is no thicker than the central region, it is thicker than the neck region which adjoins it to the lancet body.

However, any objective reading of the claims would understand that the central region of thinner section is thinner than both the peripheral thickened region and the further thickened region. The claims have also been amended to better reflect this fundamental difference over MORITA.

The other applied art references fail to address the above-described deficiencies of MORITA.

As a result, MORITA fails to teach each and every limitation of claim 12 of the present invention. MORITA thus fails to anticipate claim 12 of the present invention. Claims depending upon claim 12 are patentable for at least the above reasons.

One of ordinary skill and creativity would also fail to produce a claimed embodiment of the present invention from any combination of MORITA with the secondary references, and a *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

**Rejections Based on LEVIN**

Claims 12, 14, 15 and 17 have been rejected under 35 USC §103(a) as being unpatentable over LEVIN in view of HIGGINS. Claims 13 and 16 have been rejected under 35 USC §103(a) as being unpatentable over LEVIN in view of HIGGINS, and further in view of CROSSMAN. These rejections are respectfully traversed.

LEVIN pertains to a single use lancet. The Official Action refers to Figure 10 of LEVIN, which is reproduced below.

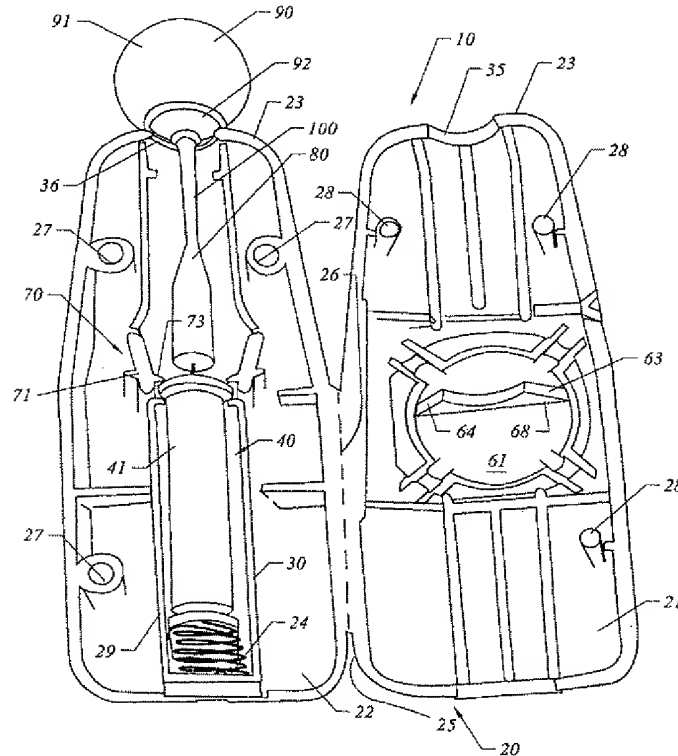


FIG. 10

Figure 10 of LEVIN shows a lancet cap in the form of a spherical external tab, i.e., a bulb, having a thin flexible stem extending to a larger thickened section surrounding the needle. The Official Action asserts that the spherical tab constitutes the peripheral tab because "although the shape of (90) is a disk, it is noted that a peripheral portion of 90 can be taken which is generally U- or C-shaped".

However, there is clearly no U- or C-shaped structure in LEVIN. There is additionally no U- or C-

shaped rib surrounding a thinner section, such as is set forth in the independent claims of the present invention.

HIGGINS and CROSSMAN fail to address these deficiencies of LEVIN.

One of ordinary skill and creativity would thus not produce claims a claimed embodiment of the present invention from a knowledge of the teachings of LEVIN and HIGGINS or LEVIN, HIGGINS and CROSSMAN. A *prima facie* case of unpatentability has thus not been made. These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

#### **CONCLUSION**

The rejections have been overcome, obviated or rendered moot, and it is believed that no issues remain. The Examiner is accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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